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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,895	03/19/2004	Madhavan Pisharodi	PISA,015	8181

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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 06/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/804,895

Applicant(s)

PISHARODI, MADHAVAN

Examiner

Paul B. Prebilic

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 3-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2 and 19-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***Election/Restrictions***

Claims 1 and 3-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 27, 2006.

Applicant's election with traverse of Group II and Species A (Figure 1) in the reply filed on February 27, 2006 is acknowledged. The traversal is on the ground(s) that no burden for examination was shown. This is not found persuasive because the product of Group I would require searching other joints for structures that read on the claimed invention while the method claims of Group II require searching method subclasses such as 623/908. Also, the new steps of "removing a portion of the intervertebral disk", "filling space . . . with a hydrogel", "sealing opening" etc. requires additional searching and examination effort.

The requirement is still deemed proper and is therefore made FINAL.

***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:  
The specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 602.

Furthermore, the declaration identifies the present application as a continuation-in-part of several applications. However, since the present application is no longer claiming 35 USC 120 benefit to earlier applications, the declaration is inconsistent with the lack of benefit being claimed.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 20, the language “the space between the implant and the portion of the intervertebral disk that has been removed” (emphasis added) is confusing and indefinite because it is unclear where the removed portion is located. Furthermore, “the space” lacks clear antecedent basis. Therefore, the Examiner suggests changing “the space” to ---a space--- and changing the underlined portion of the excerpt above to ---the two vertebrae--- in order to overcome this objection. Claims 21 and 22 have been rejected also because they are dependent upon claim 20.

***Claim Objections***

Claims 2 and 23 are objected to because of the following informalities:

With regard to claim 2, on line 7, it is unclear how a portion of the implant can be biased away from “the implant” as claimed. Rather, a portion of the implant is biased away from “another portion” of the implant. The Examiner suggests making this change to make the claim language clearer.

With regard to 23, “the opening” lacks antecedent basis. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 19, and 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Perren et al (US 6,019,793). Perren anticipates the claim language where the inserting step as claimed is met by the inserting step of Perren (see column 3, line 66 to column 4, line 2 and see column 1, line 55 to column 2, line 12), the biasing step as claimed is done by means (4) of Perren, and the restraining step is met by the fact that the device transforms from a cylindrical shape that can be rotated to a rectangular shape that conforms to the shape between the vertebrae such that rotation is inherently prevented.

With regard to claim 24, the springs as claimed are met by the connecting means (4) of Perren.

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Ralph et al (US 5,989,291). Ralph anticipates the claim language where the inserting step as claimed is disclosed by Ralph on column 5, lines 49-65, the biasing step as claimed is disclosed by Ralph on column 2, lines 43-55, and the restraining step as claimed is disclosed by Ralph on column 2, lines 56-65.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-21, 24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ralph et al (US 6,669,731) or Ralph et al (US 5,989,291) in view of Muhanna (US 6,936,070). Ralph ('731) or Ralph ('291) meets the claim language as explained in the Section 102 rejection utilizing Ralph ('291) (see *supra*) or Ralph ('731) (see Figure 5, column 2, line 52 to column 3, line 68, and column 6, lines 31-53) but fail to disclose the step of removing a portion of the intervertebral disk as claimed. However, Muhanna teaches that removal of the intervertebral disk prior to implantation of Ralph ('291) was clearly known to the art; see column 2, lines 9-22. Therefore, it is the Examiner's position that it would have been clearly obvious, if not required for operability, to remove at least a portion of the intervertebral disk in either the Ralph('731) or Ralph ('291) method to make room for the implant that replaces the structure and function of the defective disk.

With regard to claims 20-21, Muhanna teaches that it was known to fill a space around a similar implant with collagen gel, which is a type of hydrogel; see column 7, lines 3-19. Therefore, it is the Examiner's position that it would have been obvious to an ordinary artisan to fill any space around either of the Ralph implants with collagen gel

for the same reasons that Muhanna does the same or to aid in the cushioning effect desired.

With regard to claim 21, collagen gel is considered to be a protein polymer or a collagen matrix to the extent that this language can be given patentable weight.

Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ralph et al ('731), Ralph et al ('291), and Muhanna as applied to claims 19-21, 24 and 26 above, and further in view of Haldimann (US 6,428,576). Ralph ('731) or Ralph ('291) fail to disclose the use of an adhesive in the implantation method to contact the remaining disk or to seal an opening as claimed. However, Haldimann teaches that it was known to use medical grade adhesives to contact the disk and to seal openings; see Figure 1 and column 4, lines 27-48. Therefore, it is the Examiner's position that it would have been obvious to use the medical grade adhesive of Haldimann to contact the disk and to seal any openings in order to prevent migration of the implant or further herniation of the disk or for the same reasons that Haldimann utilizes the same.

### ***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.



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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Paul Prebilic", with a stylized flourish at the end.

Paul Prebilic  
Primary Examiner  
Art Unit 3738